DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October28, 2014

Lares Research
Mr. Jason Orgain
Engineering Manager
295 Lockheed Avenue
Chico, California 95973

Re: K141221
Trade/Device Name: Lares Research 557 and 757 ProStyle model product family of high-speed handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: September 26, 2014
Received: October 6, 2014

Dear Mr. Orgain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

K141221

Device Name

Lares Research 557 and 757 ProStyle model product family of high-speed handpieces

Indications for Use *(Describe)*

The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces is intended to be used by licensed dental professionals to reduce hard tooth structure, carry out cavity preparations and perform restorative dentistry.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# K141221: Section 5 - 510(k) Summary

**Submitter** **807.92(a)(1)**

Lares Research
295 Lockheed Ave
Chico, Ca 95973

Contact person: Jason Orgain
Telephone: 530-345-1767 ext 2860
Date prepared: May 7, 2014

**Device Name** **807.92(a)(2)**

Trade Names: Lares Research 557 and 757 ProStyle model product family of high-speed handpieces
Common Name: High-speed Dental Handpiece
Classification Name: High-speed Dental Handpiece
Regulation Number: 21 CFR 872.4200
Classification Code: EFB

**Predicate Devices** **807.92(a)(3)**

Predicate Device #1: Lares Research 557 Turbo+, K780038

Predicate Device #2: Lares Research 757 Workhorse, K905541

Predicate Device #3: Kavo GENTLEforce 6000B, K073478

**Device Description** **807.92(a)(4)**

The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces are the next generation of the Lares high-speed handpiece product line. The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces are substantially similar to the 557 Turbo+ and 757 Workhorse as they are light weight, air-driven high-speed turbine dental drills connected to standard ISO 9168 Type 2 and Type 3 dental unit hose connections. The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces features include a solid glass fiber optic element and optional Kavo Multi-Flex compatible swivel quick connection.

**Indications for Use** **807.92(a)(5)**

The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces is intended to be used by licensed dental professionals to reduce

hard tooth structure, carry out cavity preparations and perform restorative dentistry.

**Device Technological Characteristics** **807.92(a)(6)**

Lares Research 557 ProStyle and 757 ProStyle model product family of high-speed handpieces have ISO 9168 Type 2 connections identical to the 557 Turbo+ and 757 Workhorse, or optional Kavo Multi-Flex compatible connections equivalent to the Kavo GENTLEforce 6000B. The Lares Research 557 and 757 Pro-Style model product family of high-speed handpieces have a maximum input air and cooling fluid pressure of 40 PSI, similar to the Kavo GENTLEforce 6000B. The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces also have push button chuck operation and have optional fiber optics for lighted operation equivalent to the 757 Workhorse. Cooling fluid and atomizing spray connections are integral to the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces similar to all the predicate devices. Materials used in the construction of the Lares Research 557 ProStyle and 757 ProStyle model product family of high-speed handpieces include a stainless steel exterior and stainless steel and polymer interior (see Summary Table of Technological Characteristics).

**Summary Table of Technological Characteristics**

| Product Characteristic | Lares 557 ProStyle | Lares 757 ProStyle | Lares 557 Turbo+ (K780038) | Lares 757 Workhorse (K905541) | Kavo 6000B (K073478) |
|---|---|---|---|---|---|
| **Indications for use** | The Lares Research 557 and 757 ProStyle model product family of high-speed handpieces is intended to be used by licensed dental professionals to reduce hard tooth structure, carry out cavity preparations and perform restorative dentistry. | Identical | Equivalent | Equivalent | Equivalent |
| **Basic operation** | The handpiece is connected to a dental tubing which delivers drive air, cooling air and water to the cutting bur area. Optional fiber optics deliver light to the cutting area. | Identical | Identical | Identical | Identical |
| **Handpiece/ hose connection** | ISO 9168 type 2 or Kavo Multi-Flex compatible (optional) | ISO 9168 type 2 or Kavo Multi-Flex compatible (optional) | ISO 9168 type 2 | ISO 9168 type 2 | Kavo Multi-Flex |
| **Fiber optics** | Solid glass rod (optional) | Solid glass rod (optional) | N/A | Bundled glass fiber (optional) | Solid glass rod (optional) |
| **Handpiece head dimensions** | Head diam. = 0.410" (10.4mm) Head length =0.486" (12.3mm) | Head diam. = 0.510" (13.0mm) Head length =0.583" (14.8mm) | Head diam. = 0.400" (10.2mm) Head length =0.486" (14.8mm) | Head diam. = 0.510" (13.0mm) Head length =0.583" (14.8mm) | Head diam. = 0.493" (12.5mm) Head length =0.516" (13.1mm) |

| | | | | | |
|---|---|---|---|---|---|
| **Overall handpiece length** | 4.61" (117.1mm) - Multi-Flex compatible; 5.46" (138.7./mm) - ISO 9168 Type 2 connection | 4.75" (120.7mm) - Multi-Flex compatible; 5.59" (142.0/mm) - ISO 9168 Type 2 connection | 5.50" (139.7/mm) - ISO 9168 Type 2 connection | 5.60" (142.2/mm) - ISO 9168 Type 2 connection | 4.67" (118.6mm) Multi-Flex connection |
| **Type of chuck** | Friction grip Push-button | Friction grip Push-button | Friction grip Wrench type | Friction grip Push-button | Friction grip Push-button |
| **Materials used in patient-contact surfaces (external)** | Stainless steel | Stainless steel | Stainless steel | Stainless steel | Information not available |
| **Materials used in the water and air passages (internal)** | Stainless steel, polyphenylsulfone (PPSU) | Stainless steel, polyphenylsulfone (PPSU) | Stainless steel | Stainless steel | Information not available |
| **Operating pressure** | 32 - 40 PSI | 32 - 40 PSI | 32 - 40 PSI | 32 - 40 PSI | 30 - 51 PSI, 40 PSI recommended |
| **Free-running speed** | 450-510 kRPM | 340-400 kRPM | 450-510 kRPM | 340-400 kRPM | 370 kRPM |
| **Compliance Standards** | Complies with ISO 14457 | Complies with ISO 14457 | Complies with ISO 7785-1 | Complies with ISO 7785-1 | Complies with ISO 7785-1, ISO 7405, ISO 9168 |

## Nonclinical Tests Discussion 807.92(b)(1)

Nonclinical tests included:

Performance tests in accordance to international standards ISO 14457: 2012 for air-driven high-speed dental handpieces have been conducted to determine conformance to the standards for the intended use. Biocompatibility and Sterilization studies have been completed using master device samples of the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces. The master device sample Lares Research 557 and 757 ProStyle model high-speed handpiece passed all the applicable tests of ISO 14457: 2012.

## Clinical Test Discussion 807.92(b)(2)

No clinical field trials have been conducted with the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces.
Data from predicate device post market surveillance, MDR's, MAUDE, and internal Lares Research product complaint data was reviewed to identify potential safety and effectiveness issues that would need to be addressed. No additional issues were identified and the Risk Assessment report for the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces is a record of this review.

## Conclusion 807.92(b)(3)

The Lares Research 557 and 757 Pro-Style model product family of high-speed handpieces has an equivalent intended use and identical operation as well as substantially similar technological specifications as the predicate devices (Lares Research and Kavo 6000B high-speed handpiece products). The feature

updates incorporated into the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces were made to change the material of the fiber optic elements of the handpiece. Data from biocompatibility evaluations, sterilization testing and field experience of predicate devices indicate the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces pose no additional risks.

Based on the device technological characteristics comparison, nonclinical tests discussion, clinical test discussion and specification comparison the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces is substantially equivalent to the 557 Turbo+, 757 Workhorse and Kavo 6000B handpieces.

**Guidance document used:**
www.fda.gov./.../ucm142651.htm – Content of a 510(k); 510(k) Summary section. This document was used to establish the content for this section.

Format for Traditional and Abbreviated 510(K)s

This guidance document provides a process to determine which type of 510(k) submission best suits this product, and the format of the premarket 510(k) document. Based on the information provided, Lares Research determined the Abbreviated 510(k) would be best suited. Specific recommended forms and section headers indicated in this guidance document were used to create the basic formatting for the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces 510(k) document. Any guidance document listed as a reference for further information in each section was also reviewed and included in this premarket 510(k) document as needed.

Bundling Multiple Devices or Multiple Indications in a Single Submission

This guidance document was used to determine if the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces could be bundled into a single premarket notification. Based on the discussion in Section B of this guidance document, it was decided that the Lares Research 557 and 757 ProStyle model product family of high-speed handpieces has equivalent indications for use and substantially equivalent performance and technological characteristics, which would allow all Lares Research 557 and 757 ProStyle model product family of high-speed handpieces to be bundled into one 510(k) premarket notification.

Dental Handpieces – Premarket Notification [510(k)] Submissions

This guidance document provided specific dental product references for formatting and for information to be included in each section of the 510(k) document. This document also provided a list of standards which are recognized by the FDA for this product code. Specific performance and construction information recommended in this guidance document was also included in the 510(k) premarket notification document.

## K141221: Section 5 - 510(k) Summary

The New 510(k) Paradigm, Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.

This guidance document was used to structure the data supporting substantial equivalence between existing legally marketed products and Lares Research 557 and 757 ProStyle model product family of high-speed handpieces.